REMARKS

The above-captioned application is a continuation of PCT/AU99/00867, which claims priority to Australian Provisional Patent Application No. PP6646. The present invention relates to microprojectile bombardment using plant DNA directly isolated from a donor plant to produce transformed plants.

Claims 22-42 are pending in the application. Claims 1-21 were canceled and claims 22-42 were added by preliminary amendment. Claims 32-42 were withdrawn from further consideration as being drawn to a non-elected invention. Therefore, claims 22-31 are presently under consideration.

Claims 22, 23, 24, and 25 have been amended herein to more particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Support for these amendments is found throughout the specification as filed as more fully set forth below. Thus, no new matter has been added by way of these amendments. Further, the specification as been amended to recite the claimed priority and a substitute page 1, reciting the claimed priority, is attached hereto.

Objection to the Specification

The Examiner, at page 2 of the Office Action, has objected to the specification stating that the claimed priority is not set forth in the application. Applicants have amended page 1 of the specification to state the claimed priority, thereby overcoming this objection. No new matter has been added by way of this amendment.

Rejection of Claim 31 under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claim 31 for lack of written description. More specifically, the Examiner asserts that Applicants do not identify or describe the genes that have been transformed into the recipient cell, the characteristic structural features inherent to the genes, nor the phenotype of the recipient cell.

Applicants, while not necessarily agreeing with the Examiner's reasoning, in a good faith effort to expedite prosecution of this application, have amended claim 22, from which claim 31 depends, to recite "plant DNA" instead of "gene." This amendment introduces no new subject matter and is supported throughout the specification and claims as

filed (e.g., specification at page 4 line 18 to page 5, line 3, pages 7-19, Tables 3 and 4, Figures 1 and 2).

Applicants respectfully submit that claim 31, as amended, is amply supported by the specification as filed and that the claim complies with the written description requirement of 35 U.S.C. §112, first paragraph, for the following reasons.

It is settled law that the written description requirement is viewed in light of the state of the art and skill of the practitioner at the time the application was filed. In *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991), the Court of Appeals for the Federal Circuit traced the development of the written description requirement under 35 U.S.C. §112, first paragraph. The *Vas-Cath* Court, in a unanimous opinion, noted approvingly that in a written description analysis, "[t] he primary concern is factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure." *Vas-Cath*, 19 USPQ2d at 1116 (quoting *In re Wertheim*, 191 USPQ 90, 96 (C.C.P.A. 1976)). After discussing the policy reasons underlying the requirement, the Court set forth the standard for the written description requirement:

> The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. . . . The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter."

Vas-Cath, 19 USPQ2d at 1117 (emphasis added) (quoting *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 227 USPQ 177, 179 (Fed. Cir. 1985)). *Accord University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). Therefore, it is well-settled that the knowledge of those skilled in the art informs the written description inquiry.

In determining the sufficiency of support in a disclosure with respect to the written description requirement, "it is not necessary that the application describe the claimed invention in *ipsis verbis*; all that is required is that it reasonably convey to persons skilled in the art that, as of the filing date thereof, the inventor had possession of the subject matter later claimed by him." *In re Edwards*, 196 USPQ 465, 467 (C.C.P.A. 1978) (citing *In re Lukach*,

169 USPQ 795 (C.C.P.A. 1971); *In re Driscoll*, 195 USPQ 434 (C.C.P.A. 1977)). More recently, the Court of Appeals for the Federal Circuit, in *In re Kaslow*, 217 USPQ 1089, 1096 (Fed. Cir. 1983), citing *In re Edwards*, emphasized:

> The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language.

More recently, in *In re Alton*, 37 USPQ2d 1578, 1584 (Fed. Cir. 1996), the Court of Appeals for the Federal Circuit pointed out that literal support is not required in order to satisfy the written description requirement:

> If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met. For example, in *Ralston Purina Co. v. Far-Mor-Co., Inc.*, 227 USPQ 177, 180 (Fed. Cir. 1985), the trial court admitted expert testimony about known industry standards regarding temperature and pressure in "the art of both farinaceous and proteinaceous vegetable materials." The effect of the testimony was to expand the breadth of the actual written description since it was apparent that the inventor possessed such knowledge of industry standards of temperature and pressure at the time the original application was filed.

Therefore, it is clear that the invention need not be described in *ipsis verbis*, *i.e.*, literally, for purposes of the written description requirement under 35 U.S.C. §112, first paragraph. Rather, what is needed is that the skilled artisan understand, based upon the disclosure in the specification as filed and the knowledge imputed to the skilled artisan at the time the specification was filed, that the inventor had possession of the claimed subject matter.

Applicants respectfully submit that the skilled artisan would have understood, based upon the disclosure provided in the specification as filed, that the inventors had possession of a plant produced according to the method of claim 22, as recited by claim 31. That is because one skilled in the art would have appreciated that the invention encompasses a

recipient plant transformed by microprojectile bombardment using DNA directly isolated from a donor plant, which DNA is not present in a vector. Such methods and plants produced thereby are exemplified, and reduced to practice, in the examples, including, but not limited to, the data disclosed in Tables 1-4, Figures 1 and 2. The data disclosed in the specification as filed demonstrate that the transformed cells or tissues disclosed in the present specification comprised plant DNA from the donor plant because the AFLP results demonstrated that mature recipient plants propagated therefrom possessed integrated, donor plant DNA (see Tables 3 and 4, Figures 1 and 2, and pages 13-19). Thus, the skilled artisan, based upon the teachings provided in the specification as filed, would have understood that the invention encompassed the transformed recipient plant cell or tissue recited in claim 31, as amended, and nothing more is needed to satisfy the written description requirement of 35 U.S.C. §112, first paragraph.

Applicants further point out that the case cited by the Examiner in support of the rejection, *Regents of the Univ. of California v. Eli Lily & Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), is inapplicable with respect to the present invention. In *Regents of the Univ. of California v. Eli Lilly & Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), the Court of Appeals for the Federal Circuit held that a description of the amino acid sequence of the A and B chains of human insulin did not provide a written description of human insulin cDNA where no part of the nucleic acid sequence of human insulin was disclosed. That is, *Eli Lilly* concerned patenting of a nucleic acid encoding a specific protein of interest, *i.e.*, human insulin. The present invention does not relate to cloning of any particular gene. Rather, claim 22, from which rejected claim 31 depends, has been amended to make clear that the present invention relates to transferring plant DNA where the DNA has been isolated directly from a donor plant and is introduced into a plant cell using microparticle bombardment without a vector.

One skilled in the art, once armed with the teachings of the specification as filed, would have understood that such vector-less approach overcomes many limitations of the prior art and provides methods, and plants produced thereby, for transferring a wide plethora of plant DNA into a recipient cell. Indeed, the specification as filed, at page 16, lines 10-22, and page 19, lines 4-15, specifically notes that the novel methods of the invention do not merely transfer fully-characterized genes to a recipient plant, but instead, can be used to

transfer large amounts of uncharacterized genetic material to a donor plant. Thus, the skilled artisan armed with the teachings of the invention, would have understood that the invention encompassed a transformed recipient plant to which DNA directly isolated from a donor plant had been transferred without using a vector, and that the invention was not limited to any specific gene, features inherent to the gene, or any phenotype of the recipient cell. In addition, the specification, at page 9, lines 20-22, states that "there is no requirement that the DNA be transferred in a vector, such as typically required, and therefore does not severely restrict the number of genes which can be transferred." Therefore, Applicants respectfully submit that *Eli Lilly*, whatever its holding, is not relevant to the present invention since Applicants are not attempting to claim a particular plant transformed with a known gene; rather, the invention provides a novel approach to producing hybrid plants where plant DNA is transfected into a recipient cell or tissue without using a vector, and without the inherent limitations of recombinant DNA methods described in the prior art. Therefore, the skilled artisan would have, based upon the disclosure provided in the specification as filed, understood that Applicants' invention encompassed the subject matter recited in claim 31.

Applicants therefore submit that because skilled artisan would have understood that the invention encompassed the subject matter recited in claim 31, as amended, in accordance with the written description requirement of 35 U.S.C. §112, first paragraph, this rejection for lack of written description should be reconsidered and withdrawn.

Rejection of claims 22-27 under 35 U.S.C. § 102(b)

Claims 22-27 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hadi et al. (1996, Plant Cell Reports 15:500-505). In the Examiner's view Hadi teaches a method of transforming soybean using microprojectile bombardment with high molecular weight DNA directly isolated from maize, including a plasmid that confers resistance to the antibiotic hygromycin-B, thereby anticipating claims 22-27. Applicants respectfully submit that Hadi cannot anticipate the present invention as recited in claims 22-27.

It is well settled that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP §2131 (quoting *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). "The identical invention must be shown in as complete detail as

is contained in the . . . claim." *Id.* (quoting *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, Hadi must describe each and every element of claims 22-27 in order to anticipate these claims under Section 102(b), and this reference does not.

Applicants respectfully disagree with the Examiner's assertion that Hadi teaches transfer of high molecular weight genomic DNA. Referring to page 501 of Hadi under the "Materials and Methods" heading, Hadi states, "Plasmids bnl 14.28 and umc 29, 34, 38, 39, 82, 84, 107, 115 and 119 . . . contained RFLP markers for maize. Plasmid DNAs were prepared using alkaline lysis method and were purified by centrifugation in cesium chloride-ethidium bromide gradients." This is the DNA subsequently used for transformation of soybean tissue by Hadi. Such plasmid constructs are not high molecular weight DNA as that term is used in the art. Indeed, the skilled artisan would have understood that plasmids such as those disclosed in Hadi were isolated, purified and separated from high molecular weight, *e.g.*, plant genomic DNA, on the basis of, for instance, their buoyant density, using ethidium bromide-cesium chloride centrifugation as described in Hadi. Thus, Hadi actually teaches away from the present invention in that it relates to using vectors, more specifically, plasmid vectors, to transform plant cells.

In addition, contrary to the Examiner's assertion, there is absolutely no teaching in Hadi relating to transformation using directly isolated plant DNA, let alone using high molecular weight plant DNA. Hadi does not teach a method of plant DNA transfer including the steps of transforming a recipient plant cell or tissue by microprojectile bombardment with DNA directly isolated from a donor plant and a selection marker gene, wherein said directly isolated DNA is not present in a vector, and selectively propagating a transgenic plant from the transformed recipient plant cell or tissue by culturing said transformed recipient plant cell or tissue in the presence of a selection agent, as is claimed in amended claim 22, and claims depending therefrom. Nor does Hadi teach a method wherein the directly isolated DNA is genomic DNA. Thus, Hadi does not describe each and every element of claims 22-27 and cannot anticipate these claims.

For the reasons set forth above, Applicants respectfully submit that claims 22-27 are not anticipated by Hadi and request that the rejection of these claims under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

Rejection of claim 22, 23, 26-28, and 30-32 under 35 U.S.C. § 102(b)

Claims 22, 23, 26-8, and 30-32 stand rejected as being anticipated by Christou (1997, Plant Molecular Biology 35:197-203). It is the opinion of the Examiner that Christou teaches methods of rice transformation using microprojectile bombardment wherein DNA directly isolated from barley is transformed into rice and in another example more than one gene is transformed into rice and that this somehow anticipates the present invention. Applicants respectfully submit that Christou does not anticipate claims 22, 23, 26-28, and 30-32 under 35 U.S.C. § 102(b) for the following reasons.

As pointed out previously elsewhere herein, Christou must describe each and every element of the claims in order to anticipate these claims under 35 U.S.C. § 102(b). Applicants respectfully submit, as more fully set forth below, that Christou does not describe each and every element of claims 22, 23, 26-28, and 30-32 and cannot therefore anticipate these claims.

Preliminarily, before specifically addressing the teachings of Christou as they relate to the present invention, Applicants note that a plain reading of the abstract of Christou makes clear that the authors use the term "direct transfer" to mean transfer of "naked" DNA to distinguish from "indirect transfer" of DNA, such as, transfer involving protoplast fusion or *Agrobacterium*-mediated transformation where an intermediate organism is used. Applicants' interpretation of Christou is fully supported by the discussion of "direct DNA transfer" in Chapter 8.1 of Plant Molecular Biology: A Laboratory Manual, M.S. Clark, ed. (Springer Verlaag, 1997).

Applicants respectfully submit that there is no teaching whatsoever in Christou to transfer "DNA directly isolated from a donor plant" and "not present in a vector" as now recited by amended claim 22, from which the other claims depend. Instead, Christou, at page 200 column 1, notes that the barley *Ltp2* promoter is used to drive expression of a GUS reporter gene in a reporter construct. The *Ltp2* promoter taught by Christou is not directly isolated from a donor plant; instead, the donor DNA has been subjected to considerable manipulation and characterization and is present in a vector comprising a selected promoter. Thus, Christou cannot anticipate the present invention where the present invention does not

involve these limitations. That is, Christou does not teach a method of plant DNA transfer including the steps of transforming a recipient plant cell or tissue by microprojectile bombardment with DNA directly isolated from a donor plant, wherein said directly isolated DNA is not present in a vector. Thus, Christou cannot anticipate the present invention since it does not teach each and every element of the claims.

The Examiner also asserts that Christou, at page 201 (left column), teaches transfer of more than one gene into rice. However, this is irrelevant where Christou teaches using a vector to introduce specific genes into a recipient plant cell but does not, as recited by the rejected claim, teach the transfection of plant DNA directly isolated from a donor plant without using a vector. Thus, even assuming, *arguendo*, Christou teaches that "more than one gene is transformed into rice," this cannot anticipate the present invention where Christou requires that the genes be present in a vector and where the donor DNA is not directly isolated from the donor plant and used to transfect the recipient without need of methods involving use of plasmids or other vectors. This is because Christou, at the passage at the end of page 200 (right column), makes clear that a chimeric gene construct that included rice genomic DNA was used for analysis of integration events. Therefore, the rice genomic DNA could not have been directly isolated as recited by claim 22 since it was part of a chimeric construct. Furthermore, the construct taught by Christou was in a vector, which is further distinguished from Applicants' invention as recited in claim 22, as now amended, and in the claims depending therefrom.

Therefore, Applicants respectfully submit that Christou does not anticipate claims 22, 23, 26-28, and 30-32 under 35 U.S.C. § 102(b) and respectfully request that the rejection be reconsidered and withdrawn.

Rejection of claims 22-31 pursuant to 35 U.S.C. § 103(a)

Claims 22-31 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Christou, Hadi, and Weining et al. (1991, Theor. Appl. Genet. 82:209-216), in further view of Applicants admitted state of the prior art. More specifically, the Examiner reiterates his interpretation of the teachings of Hadi and Christou and further states that Weining teaches isolating high molecular weight DNA form a wide range of cereal crops. Further, the Examiner asserts that Applicants' stated the prior art as teaching that "Wild

members of Oryzae have been shown to be important sources of genes for improvement of yield." (Specification at page 18, lines 17-19). Thus, the Examiner then asserts that the method of Weining would be applicable to wild rice species including *Zizania*.

Applicants respectfully submit that the combination of Hadi, Christou, Weining, and the stated prior art, does not render claims 22-31 *prima facie* obvious under 35 U.S.C. § 103(a), for the following reasons.

The three-prong test which must be met for a reference or a combination of references to establish a *prima facie* case of obviousness has not been satisfied in the instant matter. The MPEP states, in relevant part:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. MPEP § 2142.

None of these criteria have been met here.

Preliminarily, Applicants' statement that "Wild members of Oryzae have been shown to be important sources of genes for improvement of yield," has been taken out of context. The very next sentence states that "However, introgression of genes from wild relatives such as *Z. palustris* to *O. sativa* has not been possible due to the considerable phylogenetic distance between such family members." Thus, the point of Applicants' statement was that the methods of the present invention overcome prior art obstacles in that, prior to Applicants' invention, such introgression had been unachievable despite the promise of improved yields held by the wild members of the *Oryzae* family. Thus, prior to Applicants' invention, the promise of the wild *Oryzae* members, which promise was noted by Xaio et al (cited at page 18 line 18 of the specification), had been unattainable for lack of methods of successfully integrating the DNA of such plants into recipient plants. The present invention solved this obstacle and has now allowed the unlocking of such promise, and the statements at page 18 of the specification as filed merely point this out. Therefore, far from

rendering the present invention obvious, the statements at page 18 note the prior art limitations now overcome by the present invention thereby emphasizing the novelty of the present invention.

As pointed out previously with regard to anticipation, neither Christou nor Hadi, nor the combination of the references, provided any motivation or suggestion as to how to transform a plant cell with DNA directly isolated from a donor plant and without using a vector. Weining, which presumably teaches a method for isolating high molecular weight DNA from a plant, does not correct the deficiencies of Christou and Hadi. Weining merely teaches isolation of high molecular weight plant DNA and proposes the use of PCR to map cereal gene polymorphisms. This reference has nothing whatsoever to do with transforming a plant or tissue thereof with the high molecular weight DNA isolated. Thus, there would not have been any motivation or suggestion, either in the art or in these references, to combine Christou, Hadi and Weining to arrive at the present invention. This is because Christou and Hadi concern using vectors to introduce plant DNA into a recipient cell and have nothing whatsoever to do with using DNA directly isolated from a donor plant to transfect a recipient cell or tissue without using a vector.

More specifically, Hadi teaches the introduction of as many plasmid constructs as technically possible using microprojectile bombardment. This teaching *ipso facto* has an upper limit in terms of the number of "genes" transferable and is therefore of little value in terms of achieving significant introgressions of donor plant DNA into recipient plant genome. Furthermore, Hadi's teaching seems to be in the direction of producing bigger and better vector constructs, which actually teaches away from the invention as presently claimed which requires no vector at all.

Christou, on the other hand, is incredibly vague. Being a review article, Christou generally describes past papers in the area of rice transformation and makes the concluding statement, at page 201 right column, that the problem facing rice transformation is that bombardment based technology is technically demanding and requires sophisticated technology, thereby disadvantaging non-industrialized countries, which is again stated at page 202 right column. More particularly, there is absolutely no disclosure of the problem overcome by the presently claimed invention let alone any coherent teaching toward the

present invention. Christou simply does not teach or suggest using DNA directly isolated from a donor plant and introducing it into a recipient without using a vector.

In further refutation of the combination of documents urged by the Examiner, Applicants note that despite being the most recent publication of those cited by the Examiner and despite being a purported review of the field, Christou makes absolutely no reference to either Hadi or Weining. Applicants submit that this further refutes that it would have been obvious to the skilled artisan to combine these references to arrive at the present invention.

Further, the combination of these references does not teach or suggest all of the claim limitations. That is, for the same reasons set forth previously, the combination of Christou, Hadi and Weining, even when combined with Applicants' statements on page 18 of the specification, do not teach or suggest all of the claims limitations. This is because, as more fully set forth previously, the combination of these references does not teach or suggest transferring plant DNA directly isolated from a donor plant into a recipient plant cell or tissue without using a vector. Thus, the combination of these references cannot render the present invention *prima facie* obvious under 35 U.S.C. 103(a).

In addition, even assuming, for argument's sake, that there would have been some motivation to combine these references, there could not have been any reasonable expectation of success from doing so. This is because, as pointed out previously, Weining is not concerned with plant transformation and does not suggest to the person of ordinary skill in the art that any of the teaching therein would be useful in improving plant transformation. Rather, it merely provides a method of isolating high molecular weight DNA from a plant and does not therefore provide the teachings missing in Christou and Hadi. In turn, Christou and Hadi do not teach or suggest use of isolated genomic DNA (whether or not isolated by the method of Weining) in the absence of a vector to improve gene introgression by microprojectile bombardment. Christou and Hadi teach use of vector based systems only, which vector systems do not use DNA directly isolated from a donor plant.

There was simply no reasonable expectation of success that the combination of these references could arrive at the invention recited in claims 22-31, as now amended. Indeed, the combination of these references illustrates that, prior to Applicants' invention, conventional wisdom had been that plant transformation by microprojectile bombardment was

best achieved using one or a few genes inserted into one or more plasmid vectors. This is the teaching of Hadi and Christou, which is not corrected by the teachings of Weining, which simply teaches a method of isolating high molecular weight DNA, but has nothing to do with transforming a plant cell or tissue with the DNA so isolated. Unlike the teachings of the combined references, the present invention shows, against the expectations of persons of ordinary skill in the art, that microprojectile bombardment of recipient plant tissue with directly isolated DNA (such as high molecular weight plant genomic DNA) in the absence of a vector can stably introduce significant introgressions of genetic material into transgenic plants. Therefore, there would have been no reasonable expectation of success that the combination of these references would produce the present invention. Thus, the rejection of these claims based on the combination of Christou, Hadi, Weining, and Applicants' statements at page 18 of the specification, constitute impermissible hindsight and cannot form the basis for a finding of *prima facie* obviousness under 35 U.S.C. §103(a).

In light of the foregoing arguments, it is clear that the above-identified references do not suggest to, or motivate, one of skill in the art to modify or combine the disclosure of said references to obtain the present invention. Nor would there have been any reasonable expectation of success in such combination since the combination of these references does not teach or suggest all of the claim limitations as required under 35 U.S.C. §103(a). Therefore, Applicants respectfully request that this obviousness rejection be reconsidered and withdrawn.

Rejection of claims 22, 25, 28, and all subsequent dependent claims pursuant to 35 U.S.C. §112, second paragraph

Claims 22, 25, 28, and all subsequent dependent claims stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully submit that the claims are not indefinite in any way as follows.

It is settled law that the "patent law allows the inventor to be his own lexicographer." *Chicago Steel Foundry Co. v. Burnside Steel Foundry Co.*, 132 F.2d 812 (7th Cir. 1943). *See also* MPEP § 2173.01. This is because "[t]he dictionary does not always keep abreast of the inventor. It cannot. Things are not made for the sake of words, but words for things." *Autogiro Co. v. U.S.*, 155 USPQ 697 (Ct. Cls. 1967). Further, applicant is entitled to

have the claims construed in connection with the other parts of the application. *See Autogiro Co. v. U.S.*, 155 USPQ 697 (Ct. Cls. 1967). Therefore, Applicants are entitled to define terms to describe their invention and the claims must be interpreted in light of the other parts of the application, including the disclosure in the specification and the definitions provided therein.

The Examiner has rejected claim 22 as being indefinite for reciting the term "gene." While not necessarily agreeing with the Examiner's reasoning, and in a good faith effort to expedite prosecution of this application, Applicants have amended claim 22 to recite "plant DNA" instead of "gene." As more fully set forth elsewhere herein, support for this amendment is found throughout the specification as filed commencing at page 7, line 10. Thus, this amendment adds no new matter. Therefore, this rejection, which noted that "a gene" was indefinite since "directly isolated DNA" could contain one or a plurality of donor plant genes, is now moot. Applicants respectfully submit that this rejection should be reconsidered and withdrawn.

Claim 22 also stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for reciting "selectively propagating." This is because, in the Examiner's view, the term is indefinite in that the criteria for such propagation is unclear such that Applicants must state how transgenic plants will be selected. Applicants, although not necessarily agreeing with the reasoning of the Examiner, and in order to expedite prosecution of this application, have amended claim 22 to recite steps comprising selective propagation. Namely, that a selection marker gene is used for microprojectile bombardment together with the directly isolated DNA and an appropriate selection agent is used to facilitate selective propagation. Support for this amendment is provided throughout the specification as filed, commencing at page 9, line 23. Therefore, this amendment adds no new matter.

Applicants respectfully submit that claim 22, as amended, is not indefinite in any way and request that this rejection under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

Claim 25 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for reciting the term "high molecular weight." Applicants respectfully submit that this term is not indefinite in any way because it is a term of art, which would have been well understood by the skilled artisan, based upon the disclosure provided in the specification as

filed. That is, the term is exemplified by, indeed, it was reduced to practice using the methods described in the very reference cited by the Examiner as providing this teaching for purposes of the obviousness rejection, *i.e.*, Weining. Moreover, Applicants refer to Chapter 2, section 4.3, in Plant Molecular Biology: A Laboratory Manual, M.S. Clark, ed. (Springer Verlaag, 1997), which is a standard treatise wherein the term "high molecular weight" plant genomic DNA is used repeatedly, further evincing that this a well-known term of art that would have been readily understood by one skilled in the art, especially in light of the disclosure provided in the specification as filed. Applicants further note that this text book chapter was incorporated by reference at page 8 of the specification as originally filed.

Thus, it is clear that one skilled in the art, provided with the teachings set forth in the specification as filed, would have understood what was meant by the term "high molecular weight" DNA as recited in term 25, and nothing further is required for purposes of 35 U.S.C. §112, second paragraph. Accordingly, Applicants respectfully submit that claim 25 is not indefinite for reciting the term "high molecular weight" and this rejection should be reconsidered and withdrawn.

The Examiner has rejected claim 28 as being indefinite for reciting the term "a cereal". Applicants do not understand the Examiner's assertion that this term is indefinite, since "cereal" is a well-known term of art referring to certain grasses producing edible grains. Applicants respectfully disagree with the Examiner's assertion and submit that "cereals" is an art-recognized term that requires no definition. That is, one skilled in the art, armed with the teachings provided in the specification as filed, would not find the term "cereals" indefinite in any way. Indeed, both Weining and Christou, cited by the Examine as prior art references, use the term repeatedly, with Weining using it in the title of the article (*i.e.*, "Identification and mapping of polymorphisms in cereals based on the polymerase chain reaction") (emphasis added). There is no need to specifically define a term used ubiquitously in the art, and which the skilled artisan would have readily understood.

Accordingly, Applicants respectfully submit that the term "cereal" is not indefinite in any way and that claim 28 is not indefinite for reciting it. Therefore, Applicants respectfully request that this rejection pursuant to 35 U.S.C. §112, second paragraph, be reconsidered and withdrawn.

Summary

Applicants respectfully submit that each objection and rejection of the Examiner to the specification and claims of the present application has been either overcome or is now inapplicable, and that each of claims 22-31 is in condition for allowance.

Reconsideration and allowance of each of these claims are respectfully requested at the earliest possible date.

Respectfully submitted,

ROBERT HENRY *ET AL.*

August 12, 2002
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Enclosures ("Marked-up" copy of the claims, "Marked-up" copy of page 1 of the specification; substitute page 1 of the specification; petition for extension of time and fee authorization therefor)

"MARKED UP" COPY OF AMENDED SPECIFICATION

On page 1, after the Title and before the paragraph entitled Field of the Invention beginning at line 4, please insert the following paragraph:

-- CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of PCT Appln. No. PCT/AU99/00897, filed October 18, 1999, which claims priority to Australian Provisional Appln. No. PP6646, filed October 22, 1998. --

"MARKED UP" COPY OF AMENDED CLAIMS

22. (Amended) A method of [gene] plant DNA transfer including the steps of:-

(a) transforming a recipient plant cell or tissue by microprojectile bombardment with:

(i) DNA directly isolated from a donor plant, wherein said directly isolated DNA is not present in a vector; and

(ii) a selection marker gene; and

(b) selectively propagating a transgenic plant from the transformed recipient plant cell or tissue obtained in step (i) by culturing said transformed recipient plant cell or tissue in the presence of a selection agent chosen according to the selection marker gene used at step (a).

23. (Amended) The method of Claim 22, wherein the selection marker gene included at step (i) is present in a selection construct [is included at step (i)].

24. (Amended) The method of Claim 22 wherein the directly isolated DNA is genomic DNA.

25. (Amended) The method of Claim 24 wherein the directly isolated DNA is a high molecular weight fraction of genomic DNA.

TITLE

NEW PLANTS FORMED BY MICROPARTICLE BOMBARDMENT WITH UNCHARACTERISED DNA

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of PCT Appln. No. PCT/AU99/00897, filed October 18, 1999, which claims priority to Australian Provisional Appln. No, PP6646, filed October 22, 1998.

FIELD OF THE INVENTION

THIS INVENTION relates to a method of gene transfer applicable to plants. More particularly, the method relates to transfer of plant DNA by microprojectile bombardment. This invention also relates to transgenic plants, and in particular transgenic *Oryza sativa* (rice).

BACKGROUND OF THE INVENTION

The transfer of desirable phenotypic traits between plants has traditionally been performed by selective breeding. Such breeding practices have been central to the development of efficient agricultural societies. More recently, recombinant DNA technology has revolutionized breeding practices, although the overall aims of conventional breeding and recombinant DNA technology are virtually identical. In fact, in hindsight it is now evident that traditional breeding practices provided a means whereby genetically-heritable phenotypic traits were introduced into plants, although in the absence of any knowledge of the genetic basis of heritability.

The underlying principle of modern recombinant DNA technology is that phenotype correlates with genotype. The resultant practical implication for genetic engineering is that transfer of a specific phenotypic trait can be achieved by transfer of a corresponding gene or genes. Accordingly, the one or more genes typically underlie phenotypic traits not normally exhibited by the plant.

As used herein, the plant which acts as a source of a gene is the "donor" and the plant into which the gene is introduced is the "recipient". A donor and recipient may be genetically distinct by virtue of being members of different species, or different cultivars, breeds, races or strains, or by being different individual members of the same species, breed, race or strain. The plant resulting from gene transfer from said donor to said recipi nt is a "transgenic" plant.

TITLE

NEW PLANTS FORMED BY MICROPARTICLE BOMBARDMENT WITH UNCHARACTERISED DNA

CROSS REFERENCE TO RELATED APPLICATIONS

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